COVIDIEN

APR 19 2012

## 510(k) Summary

Date summary prepared: 3/30/2012

**510(k) Submitter/Holder**
Covidien, formerly Valleylab, a division of Tyco Healthcare
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**Contact**
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**Name of Device**
Trade or Proprietary Name: Sonicision Sterilization Tray
Catalog Number: SCST
Common Name: Sterilization Tray
Classification Name: Sterilization wrap containers, trays, cassettes & other accessories (class II; product code KCT)

**Predicate Device**
The sterilization tray described in this submission was compared and found to be substantially equivalent to the following sterilization tray in commercial distribution:

Device Name: Sterilization Tray
Model Number: 39301 BCTS
510(k) Number: K090818 (cleared 8/18/2009)
Manufacturer: Karl Storz Endoscopy-America, Inc.

**Device Description**
The Sonicision™ Sterilization Tray (SCST) is intended to hold and protect Sonicision generators and battery packs during sterilization and storage, as indicated. It is comprised of a polysulfone base containing silicone inserts and a removable/latching polysulfone lid. The tray is reusable and provided to the customer in a non-sterile condition. Perforations on the lid and base permit exposure of the sterilant. The tray containing the intended content/load must be wrapped with an FDA-cleared STERRAD® sterilizer-compatible polypropylene sterilization wrap (not supplied by Covidien) and sterilized as instructed by the labeling. Handles on the sides of the base facilitate transfer of the sterilized components, and the contoured inserts secure the contents within the tray.

Important note: the tray is not considered a reusable rigid sterilization container (per the definition found in clause 3.4 of the ST77 standard) – it does not contain gaskets, filters, or valves to act as a barrier to microorganisms during storage, handling, and transport. It must be enclosed in a sterilization wrap in accordance with the instructions for use.

**Intended Use**
The Sonicision Sterilization Tray (SCST) is intended to be used to encase and protect reusable battery packs (SCB) and generators (SCG) of the Sonicision system during sterilization and storage. The tray containing up to one generator and one battery pack (Maximum Load) can be used with the STERRAD® 100S model and pre-set (non-adjustable) Standard cycle. The tray within its sterile barrier is intended to maintain sterility for up to 30 days.

**Technological and Performance Characteristics**
The Sonicision and Karl Storz sterilization trays were found to be similar in many ways. The following three essential relevant similarities were identified and discussed in the submission: (1) Intended use – specifically, the indications for use of both trays are nearly identical, which is to encase and protect specific reusable medical devices during low-temperature hydrogen peroxide gas plasma (STERRAD®) sterilization and subsequent storage. (2) Basic design and material characteristics – both trays are comprised of polysulfone and designed as a two-part (lid/base) system with latches, handles, perforations, and contoured silicone inserts designed to hold specified content. And (3) cleaning and sterilization – the cleaning and sterilization processes of both trays are very similar. The detailed instructions provided in the labeling require the device to be thoroughly cleaned, rinsed, dried, inspected, and wrapped prior to sterilization. Notably, both trays assure adequate sterility of their content when used as instructed.

Comparison of the Sonicision and predicate device sterilization trays found very few differences. None of the differences (e.g., geometry, size, weight, intended content) were found to be relevant to the potential impact on safety or effectiveness. Two potentially relevant differences are acknowledged: (1) The percent of total surface area perforations and (2) latching mechanism materials and design. These differences do not impact safety or effectiveness – both devices achieve a sterility assurance level of at least $10^{-6}$, and the Sonicision tray's latching mechanism performs adequately to secure the lid to the base.

**Non-Clinical Performance**
The Sonicision sterilization tray conforms to applicable clauses of FDA-recognized consensus standard AAMI ST77:2006 and draft FDA Guidance Document, "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities; Draft Guidance for Industry and FDA" (March 7, 2002). Conformance to this standard and guidance document rely on adherence to the requirements and procedures of the following national and international standards: ISO 10993-1:2003, AAMI ST81:2004, ISO 14937:2000, and ISO 14971:2007. Declarations of Conformity to the guidance document and standard were provided in the submission.

**Clinical Performance**
This premarket notification report does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

**Conclusion**
Data submitted in this premarket notification report demonstrate that the subject device (Sonicision Sterilization Tray [SCST]) is at least as safe and effective and, therefore, substantially equivalent to the predicate device with regard to intended use, technological characteristics, and non-clinical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David M. Horton
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APR 19 2012

Re: K112536
Trade/Device Name: Sonicision Sterilization Tray, Model SCST
Regulation Number: 21 CFR §880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: April 17, 2012
Received: April 18, 2012

Dear Mr. Horton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K112536

Device Name: Sonicision™ Sterilization Tray

Indications for Use:
The Sonicision Sterilization Tray (SCST) is intended to be used to encase and protect reusable battery packs (SCB) and generators (SCG) of the Sonicision system during sterilization and storage. The tray containing up to one generator and one battery pack (Maximum Load) can be used with the STERRAD® 100S model and pre-set (non-adjustable) Standard cycle. The tray within its sterile barrier is intended to maintain sterility for up to 30 days.

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|---|---|---|
| Prescription Use _____<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use ✓<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth P. Clarvis-Wells

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K112536